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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,840	02/16/2007	Yasufumi Kikuchi	060641-0113	2215

22428 7590 10/07/2009

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,840	KIKUCHI ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 8/27/09, is acknowledged.

2. Claims 23-43 are pending.

3. Only claims 38 and 41 read on the original presentation of a humanized antibody binding to CD47 and a therapeutic agent thereof and the humanized MABL-2 antibody HL5, SEQ ID NO: 73 (now SEQ ID NO: 110/113), HCDR1-3 of SEQ ID NO: 37 (now SEQ ID NO: 100) and LCDR1-3 of SEQ ID NO: 7 (now SEQ ID NO: 93) as the species

Upon reconsideration the Examiner has extended species election to cover SEQ ID NOs: 99 and 106 of claims 23-33 and 39-40.

4. Claims 34-37 (SEQ ID NO: 90, 92 non-elected species) are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. It is noted that SEQ ID NO:99 and 106 dose not further comprises SEQ ID NO:90, 92 as recited in claims 34-37. For example, VH FR1 (aa 1-30 of SEQ ID NO: 99) can not be found in SEQ ID NO: 90 or 92.

5. Claims 23-33 and 38-43 are under consideration in the instant application are under examination as they read on a humanized antibody binding to CD47 and a therapeutic agent thereof and the humanized MABL-2 antibody HL5, SEQ ID NO: 73 (now SEQ ID NO: 110/113), HCDR1-3 of SEQ ID NO: 37 (now SEQ ID NO: 100/113) and LCDR1-3 of SEQ ID NO: 7 (now SEQ ID NO: 93) and SEQ ID NO: 99 and 106 as the species.

6. Claims 26, 27 and 43 are objected to because the term "any one of claims X", is not clear. Claims 27-6 and 27 refers to only one claim not multiple claims as recited. Claim 43 recites the same diseases twice. Further claim 43 has to periods.

7. The following new ground of rejections are necessitated by the amendment submitted 8/27/09.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 23, 25, 26, 28, 30, 32 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The combination of the CDR1-3 and FR1 and FR2 of SEQ ID NO: 99 and the combination of CDR1-3 and FR2 of SEQ ID NO: 106 claimed in claim 23, and the phrase "wherein the sequence of aa 40-54(FR2) of SEQ ID NO:106 is replaced with the sequence of aa 159-175 (FR2) os SEQ ID NO: 92" claimed in claim 25 represent(s) a departure from the specification and the claims as originally filed.

Applicant's amendment filed 8/27/09 points to the specification at original claims 4 and 5 and the specification on page 70, ¶151 for support for the newly added limitations and combination of CDRs with FR as claimed in claim 23 and 25. However, the specification does not provide a clear support for such limitation. The specification does not contemplate a mix and match of heavy and light chain FR1-3 as claimed in claim 23, nor does the specification contemplate a replacement of (aa 40-54, SISCRSSQSLVHSNG) L-FR2 with the (aa 159-175, YLHWYLQKPGQCPRLLI, L-CDR2 + FR3) CDR2 of SEQ ID NO: 92. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

10. Claims 39-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a humanized antibody binding to human CD47, MABL-2 antibody HL5, SEQ ID NO: 110/113) comprising HCDR1-3 of SEQ ID NO: 99 and LCDR1-3 of SEQ ID NO: 106 and the humanized antibody binding to CD47 comprising VH of SEQ ID NO: 99 and and VL of SEQ ID NO: 106 or a therapeutic agent thereof, does not reasonably provide enablement for the intended use of the therapeutic agent for a hematological disorders recited in claims 39-43. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant fails to address this rejection in the remarks filed on 8/27/09. The rejection is reiterated for Applicant's convenient.

At issue is the claimed therapeutic agent for hematological disorders, the specification under Example 7 on pages 73-74 discloses the efficacy test of the humanized MABL-1 antibody sc(Fv)2 on leukemia model animals. However, no results were shown. Further, the specification under example 7(4) and Figure 21 evaluated the antitumor effect of humanized MABL-1, wherein humanized MABL-1 anti-CD47 antibodies were found to show antitumor effect. However, it is not clear that the antitumor effect of the humanized MABL-2 present the hematological disorders claimed.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 24, 27, 29, 31, 33 and 38 are allowable.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 5, 2009

/Maher M. Haddad/
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